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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/786,951   | 02/24/2004  | Daniel Henry Densham | GJE-35D1            | 5474             |
| 23557  | 7590        | 02/08/2006           | EXAMINER            |                  |
| SALIWANCHIK LLOYD & SALIWANCHIK<br>A PROFESSIONAL ASSOCIATION<br>PO BOX 142950<br>GAINESVILLE, FL 32614-2950 |             |                      | SISSON, BRADLEY L   |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1634                 |                     |                  |

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                       |  |
|------------------------------|------------------------|-----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>   |  |
|                              | 10/786,951             | DENSHAM, DANIEL HENRY |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>       |  |
|                              | Bradley L. Sisson      | 1634                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 09/463,549.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/24/04, 7/12/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1-18 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 3-17, 21, and 30-37. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
2. Claims 1-18 of this application conflict with claim s1, 3-17, 21, and 30-37 of Application No. 09/463,549. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

4. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

5. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim s1, 3-17, 21, and 30-37 of copending Application No. 09/463549. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '549 application fairly teach and suggest the claimed method of sequencing a polynucleotide wherein one reacts a target polynucleotide and an immobilized polymerase wherein a blocking group can be removed by the use of monochromatic light. In view of the detailed teachings, one of ordinary skill in the art

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would have been motivated to have devised the claimed method and would have also had a most reasonable expectation of success.

7. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written-description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572.

10. For convenience, claim 1, the sole independent claim pending in the instant application, is reproduced below.

1. A method for sequencing a polynucleotide, comprising the steps of:

(i) reacting a target polynucleotide with a polymerase enzyme immobilized on a solid support, and complementary nucleotides, under conditions sufficient for the polymerase reaction; and

(ii) detecting an effect consequent on the incorporation of a specific nucleotide complementary to the target polynucleotide by measuring a change in or absorption of applied radiation that occurs during the incorporation.

11. For purpose of examination, the method of claim 1 has been interpreted an encompassing the determination of any length of polynucleotide, including full-length chromosomes. Said method has also been interpreted as encompassing the simultaneous sequencing of an infinite number of polynucleotides that are present in a single mixture.

12. The claimed method has also been interpreted an encompassing both direct and indirect immobilization of any polymerase on any solid support. Such language has been further construed as to encompass the binding of the polymerase to a target polynucleotide, where the target polynucleotide is directly or indirectly bound to the solid support.

13. The claimed method has also been construed as encompassing the determination of the complete nucleotide sequence where no blocking step is performed, and where all possible nucleotides are present in a given mixture, thereby allowing for full length transcripts.

14. The specification has not been found to set forth in "such full, clear, concise, and exact terms" a reproducible method whereby any nucleic acid could be sequenced to completion, wherein said nucleic acid can be of virtually any length, that the nuclei acid be present in a

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heterogeneous mixtures of other polynucleotides, and/or where all possible nucleotides are present and nascent sequences are allowed to develop unimpeded.

15. In accordance with claim 7, the method employs a blocking group at both the 3' terminus and the terminal phosphate, with selective removal of the terminal phosphate. Page 7, last paragraph, of the specification states in part that "the blocking groups should be capable of being distinguished on the basis of their spectral absorbency, i.e., it should be possible to remove selectively one of the blocking groups..." The aspect of the specification teaching as to what might, could, or should be possible does not reasonably suggest that applicant was in possession of this aspect o the invention at the time of filing. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

16. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

17. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in

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the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

18. For purpose of examination, the method of claim 1 has been interpreted an encompassing the determination of any length of polynucleotide, including full-length chromosomes. Said method has also been interpreted as encompassing the simultaneous sequencing of an infinite number of polynucleotides that are present in a single mixture.

19. The claimed method has also been interpreted an encompassing both direct and indirect immobilization of any polymerase on any solid support. Such language has been further

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construed as to encompass the binding of the polymerase to a target polynucleotide, where the target polynucleotide is directly or indirectly bound to the solid support.

20. The claimed method has also been construed as encompassing the determination of the complete nucleotide sequence where no blocking step is performed, and where all possible nucleotides are present in a given mixture, thereby allowing for full length transcripts.

21. Of the examples provided, that found at page 14, bridging to page 15 of the disclosure is most relevant to the claimed method. As set forth therein the results obtained are presented in Figure 2. For convenience, Fig. 2a is reproduced below.

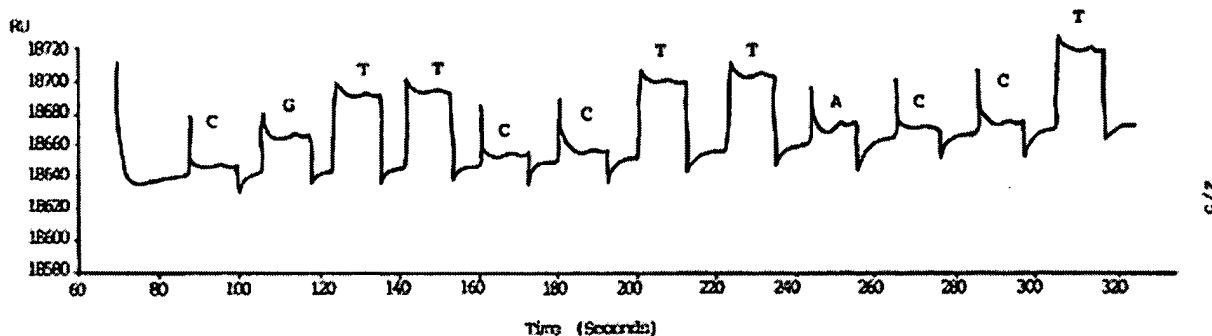


Fig. 2a

22. It is evident from the disclosure, including Fig. 2a, that but a single template was being sequenced, and then the nucleotide sequence was determined at a rate of about 1 nucleotide per 20 seconds. Significantly, but a single nucleotide was incorporated into the complementary strand at a time, and that further nucleotide addition was proscribed due to the presence of a blocking group in the 3' position.

23. The specification does not set forth a reproducible procedure whereby dual blocking groups are present and are selectively removed.

24. It is evident that the template is being held in place due to interaction with the immobilized polymerase. The aspect of density of template on any given area of the surface of the solid support, as well as the length and ability to form self-self duplex structures speaks to significant issues of operability and functionality. A review of the specification fails to find any teaching of how dense a target sequence can be applied to a surface, as well as to limitations of the length of same so as to avoid self: self duplex structures which in turn would block effective primer extension reactions.

25. In view of the breadth of scope claimed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are not enabled by the disclosure. Therefore, and in the absence of convincing evidence to the contrary, claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

#### ***Double Patenting***

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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27. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

28. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

29. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,623,929 B1 (Densham). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claimed methods are predicted upon the synthesis of polynucleotides and are interrogated through the use of surface plasmon resonance.

30. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 11, 12, 16, 17, 21, and 22 of copending Application No. 10/478,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a method of sequencing a polynucleotide.

31. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
06 February 2006